

Translation

PATENT COÖPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference BMM271WO	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/DE2004/001571	International filing date (day/month/year) 16.07.2004	Priority date (day/month/year) 18.07.2003
International Patent Classification (IPC) or national classification and IPC A61L24/06		
Applicant BIOMET DEUTSCHLAND GMBH		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **6** sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of _____ (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I	Basis of the report
<input type="checkbox"/>	Box No. II	Priority
<input type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 25(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI	Certain documents cited
<input type="checkbox"/>	Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

PCT/DE2004/001571

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-4 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-6 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following documents:

D1 EP-A-0 985 413
D2: US-B-6 494 7171
D3: US-A-4 797 282
D4: US 2002/041899
D5: WO 01/12242
D6: EP-A-0 450 117
D7: US-A-5 942 218

The relevant passages are cited in the international search report.

1. Novelty

None of the documents listed in the international search report describes exactly the composition consisting of a PMMA bone cement and the active ingredient polyhexamethylene biguanide with a concentration of at most 1 mass % relative to the total quantity of cement. The independent claims and the claims that are dependent thereon thus meet the requirements for novelty (PCT Article

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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33(2)).

2. Inventive step

The present application meets the requirements of PCT Article 33(1) because the subject matter of claims 1 to 6 involves an inventive step (PCT Article 33(3)).

The essence of the present invention lies in the unexpected results of the combination of PMMA cement and polyhexamethylene biguanide (PHMBG), since active ingredients with a high molecular weight (MW 2000 to 15000) are usually only relatively poorly released or practically not at all owing to their size. It would therefore not have been expected that the populating of bacteria on the cement could be so well suppressed using such small quantities of added PHMBG of high molecular weight.

Document D3 is considered the closest prior art. D3 describes the use of chlorhexidine (also from the biguanide family) in a bone cement. However, chlorhexidine is a biguanide derivative of low molecular weight (MW 505) and can be released more easily. Therefore, a person skilled in the art would not arrive at the use of PHMBG in bone cements from D3.

D1 does not indicate the use of PHMBG in bone cement and in particular not the use of such small

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quantities (no pharmacological quantities of active ingredients are indicated).

D2 also describes the use of chlorhexidine or alexidine in compositions for treating calcified tissue. Like chlorhexidine, alexidine has a low molecular weight (MW 508).

D4 also describes the use of chlorhexidine or alexidine in compositions for coating implants or cements.

D5 describes a mineral cement that contains Lavasept. Since mineral cements have a higher water content, the water-soluble active ingredients are released using different kinetics.

D6 and D7 describe only the use of PHMBG in solutions that are used to disinfect bone wounds. Use in bone cements which are made specifically from PMMA and at such a low concentration is not suggested.

The current invention is considered inventive owing to the high molecular weight and the small quantity of PHMBG required.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The phrases in claim 3, "does not cause lasting deterioration" and "does not substantially impair" are vague and unclear and leave the reader uncertain as to the meaning of the technical features in question. As a result, the subject matter of said claim is not clearly defined (PCT Article 6).

Claim 6 does not meet the requirements of PCT Article 6 because the subject matter for which protection is sought is not clearly defined. The product is defined in terms of the product from claims 1 to 5, but claims 1 to 5 describe a use, not a product. The subject matter of claim 6 is therefore not clearly defined (PCT Article 6).